

Service evaluation of the Changing Health Structured Education and Lifestyle Behaviour Change Coaching Programme for Prevention of Diabetes

Introduction

Type 2 diabetes has emerged as a major health challenge affecting an estimated 380 million adults across the globe¹. In the United Kingdom, 3.7 million people have been diagnosed with the condition² and this number is expected to reach 5 million by 2025 in the absence of effective measures to stem the tide³. An additional 12.3 million people in the UK are also at increased risk of developing type 2 diabetes⁴. Diabetes caused 1.5 million deaths in 2012, while elevated blood glucose levels caused an additional 2.2 million deaths primarily by increasing the risk of cardiovascular and other diseases⁵.

Uncontrolled or poorly controlled diabetes can lead to serious complications and increase the risk of premature death. Complications include kidney failure, diabetic retinopathy, foot ulcers, infections and possibly amputation of limbs, nerve damage and an increased risk of heart attacks and strokes. The management and treatment of complications also places severe strains on national health systems. In 2012, the UK's National Health Services (NHS) spent £23.3 billion in direct and indirect costs on type 2 diabetes and this expenditure was projected to increase to £35.3 billion by 2035/36⁶.

While type 2 diabetes is caused by insulin resistance or insufficient production of insulin by the pancreas, there are risk factors that increase the likelihood of developing the condition. Overweight/obesity and physical inactivity are two important modifiable risk factors and targeting these risk factors can potentially help prevent type 2 diabetes, thus saving lives, preventing complications and reducing spend by health systems.

¹https://www.who.int/diabetes/global-report/WHD2016_Diabetes_Infographic_v2.pdf?ua=1 (90% of those with diabetes have type 2 diabetes.)

²<https://www.diabetes.org.uk/professionals/position-statements-reports/statistics/diabetes-prevalence-2017>

³<https://www.diabetes.org.uk/professionals/position-statements-reports/statistics>

⁴<https://www.diabetes.org.uk/professionals/position-statements-reports/statistics>

⁵http://apps.who.int/iris/bitstream/handle/10665/204871/9789241565257_eng.pdf;jsessionid=99245F46F8C28D6B4FB0D21ED7AA45D2?sequence=1

⁶Hex, N., Bartlett, C., Wright, D., Taylor, M., & Varley, D. (2012). Estimating the current and future costs of Type 1 and Type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs. *Diabetic Medicine*, 29(7), 855-862.

Changing Health develops and delivers evidence-based behaviour change programmes^{7 8 9} for people living with and at risk of type 2 diabetes. The 12-month programmes consist of structured education delivered digitally via a mobile or web app and remote lifestyle coaching delivered by coaches trained in behaviour change techniques via telephone. In this service evaluation, we investigated the effectiveness of Changing Health's programme on weight loss among overweight/obese participants who did not have a diagnosis of type 2 diabetes but were at a higher risk of developing the condition.

Methods

Study Design

This evaluation was designed as a two-arm 12 month randomized study to assess the effectiveness of the Changing Health programme without or with a low calorie diet on weight loss and other participant-reported health measures among individuals living across the UK. Participants were recruited via the Changing Health website (www.changinghealth.com) where they completed an online registration form to express interest in participation.

To be eligible, individuals had to be over the age of 18 years, have access to the internet and a computer or mobile phone (iPhone or Android), not be pregnant or breastfeeding, not be on insulin, not have contraindications for weight loss or physical activity, and had to complete the baseline assessment.

Randomization

Eligible participants were randomly assigned to one of two groups - Changing Health (CH) or Changing Health + low calorie diet (CH + LCD). We randomly assigned study participants to the CH and CH + LCD groups in a 2:1 ratio using a computer generated assignment schedule. Randomization was done in blocks of 6 to ensure balance in distribution of participants in the study groups. Because of the nature of the interventions, participants, the study coordinator and the team delivering the interventions could not be blinded to study assignment.

Interventions

Upon completion of the online screening survey, all eligible participants were sent an online baseline survey, following whose completion they were randomized to one of the two study groups. Participants in both study groups received a 12 month programme which provided them access to the Changing Health app which provided six structured education modules that included animations, articles and interactive exercises focused on the biology of type 2

⁷Deakin, T. A., Cade, J. E., Williams, R., & Greenwood, D. C. (2006). Structured patient education: the Diabetes X-PERT Programme makes a difference. *Diabetic Medicine*, 23(9), 944-954.

⁸ Avery, L., Charman, S. J., Taylor, L., Flynn, D., Mosely, K., Speight, J., ... & Trenell, M. I. (2015). Systematic development of a theory-informed multifaceted behavioural intervention to increase physical activity of adults with type 2 diabetes in routine primary care: Movement as Medicine for Type 2 Diabetes. *Implementation Science*, 11(1), 99.

⁹Avery, L., Flynn, D., Dombrowski, S. U., van Wersch, A., Sniehotta, F. F., & Trenell, M. I. (2015). Successful behavioural strategies to increase physical activity and improve glucose control in adults with Type 2 diabetes. *Diabetic Medicine*, 32(8), 1058-1062.

¹⁰Avery, L., Flynn, D., Van Wersch, A., Sniehotta, F. F., & Trenell, M. I. (2012). Changing physical activity behavior in type 2 diabetes: a systematic review and meta-analysis of behavioral interventions. *Diabetes care*, 35(12), 2681-2689.

diabetes, lifestyle modifications through diet and physical activity and behaviour change strategies. The app also allowed participants to log their weight, take pictures of their meal and tag it green or red (depending on whether the participant perceived the meal to be healthy or unhealthy), and track their steps. Participants also received 100 minutes or 9 appointments (1x 20 minute introductory call followed by 8 x 10 minute calls to be booked at a frequency and time of the participant's choosing provided the coach was available) with their lifestyle behaviour change coach. Appointments with the coach could be booked via the Changing Health app. In addition to the 12 month programme, participants in the CH + LCD group received the Carbs & Cals Very Low Calorie Recipes & Meal Plans book (Chris Cheyette and Yello Balolia) and were advised by their coaches to consume 1,200 - 1,600 calories per day.

Outcomes

Our primary outcome of interest was weight loss at each assessment time-point (months 1, 2, 3, 6, 9 and 12). Since clinically significant weight loss has a more meaningful impact on health, we also assessed the percentage of participants achieving 3% and 6% weight loss at each time-point. Other outcomes included participant-reported changes in diet and physical activity, quality of life (measured by the Australian Quality of Life AQoL-8D)¹¹, diet (measured by the Diabetes Dietary Questionnaire)¹². We also assessed various implementation measures such as uptake of the app, completion of the structured education programme, and use of the coaching element of the programme. Participant feedback on education, app features, and satisfaction with coaching and the overall programme were also captured. All participant-reported outcomes were assessed by online surveys sent out to participants at months 1, 2, 3, 4, 6, 9 and 12. Weight loss was assessed only among survey completers. Implementation measures are based on app usage data extracted from the Changing Health database.

Findings

468 interested individuals from across the UK registered on the Changing Health website between September - December, 2017 to participate in the service evaluation. 207 completed the online screening survey, of which 194 participants were found to be eligible. 149 eligible respondents completed the online baseline survey and were randomized to the CH group (N = 97) and CH + LCD group (N = 52). The mean age of participants was 55 years, and 130 (85%) were female. Most participants (91%) were of White or White British ethnicity, and a majority (65%) had a degree, postgraduate degree or professional qualifications. The mean BMI was 28.5 kg/m² (well within the overweight range) and 63% of participants were overweight or obese, thus increasing their risk of type 2 diabetes and other chronic conditions (Table 1).

¹¹Richardson J., Iezzi A., Khan M.A., & Maxwell A. (2013). Validity and reliability of the Assessment of Quality of Life (AQoL-8D) multi attribute utility instrument. *The Patient: Patient-Centered Outcomes Research*, doi: 10.1007/s40271-013-0036-x

¹²England, C. Y., Thompson, J. L., Jago, R., Cooper, A. R., & Andrews, R. C. (2017). Development of a brief, reliable and valid diet assessment tool for impaired glucose tolerance and diabetes: the UK Diabetes and Diet Questionnaire. *Public health nutrition*, 20(2), 191-199.

By the conclusion of the study, 21 participants (22%) from the CH group and 10 participants (19%) from the CH+LCD group had notified the study team about their intention to drop out of the study. At the key time-points of 6 and 12 months, 52 (35%) and 34 (23%) participants respectively completed the online surveys.

Most study participants (89%) became active within the app by logging in. 104 (70%) of all participants completed the structured education modules defined as completing 4 or more of the 6 modules. 53% of all participants accessed behaviour change coaching, whereas 15% declined coaching (Table 2).

Participants showed steady weight loss across the entire study duration starting with an average weight loss of 1kg in month 1, 3.3kg in month 6, and 4.5kg in month 12 (Table 3). Weight loss in the CH + LCD group was greater than the CH group, although statistical significance was not assessed because of the small sample sizes.

The percentage of participants achieving weight loss of 3% or more also increased from months 1 to 9 (16% to 63%), showing a drop in month 12 (56%) (Table 4). In the first month of the intervention ~10x as many participants in the CH+LCD group achieved 3% weight loss compared to the CH group indicating that the low calorie diet can help to initially jump start weight loss. However, by month 12, these differences were no longer visible (57% in CH vs. 56% in CH+LCD), suggesting that weight loss in the CH group might be slower and sustained. Similar results were observed for percentage of participants achieving 6% weight loss (Table 5).

Most participants (95%) reported that the education content was easy to understand. While a majority (64%) reported that the diet tracker was easy to use, only 44% found it valuable, suggesting that the value of this tool was not being clearly communicated. 82% felt that coaching was essential to their success in the programme, and 82% were also satisfied with coaching. Overall, 82% of participants were satisfied with the programme and reported that they would recommend it to others (Table 6).

Discussion

The Changing Health programme without or with the low calorie diet resulted in a weight loss of 5kg, and ~30% of participants achieved $\geq 6\%$ weight loss at 12 months. Weight loss in the CH+LCD group was faster in the earlier months of the intervention and the percentage of participants achieving clinically significant weight loss was also greater than that in the CH group. This suggests that by providing the Carbs & Cals Very Low Calorie Recipes & Meal Plans book in conjunction with the Changing Health programme, we could potentially encourage otherwise unmotivated participants by demonstrating early results.

The percentage of participants achieving clinically significant weight loss increased from months 1 through 9, but then decreased in month 12. This decrease was driven largely by the reduction in these numbers in the CH+LCD group, as the percentages continued to increase in the CH group at month 12 compared to month 9 (57% vs. 53% for 3% weight loss and 21% vs. 18% for 6% weight loss). Participants completed the month 12 survey during the holiday season, when it might not have been easy to adhere to 1,200 - 1,600

calories/day. Whether this effect is real or simply a consequence of the timing of the measurement will need to be investigated in other studies.

Like other studies focused on weight loss, our study is limited in the fact that participants volunteered to be part of this evaluation and are therefore more likely to be motivated to lose weight. Therefore, our results might not be generalisable to the average overweight/obese population. Another limitation is that because the intervention was delivered remotely, no in-person study visits were conducted because of which no clinical measures such as Hba1c, BP, lipids etc could be recorded to more carefully assess the impact of the intervention on participant health. Finally, our study was not powered to assess statistically significant differences in weight loss between the CH and CH+LCD group. A larger randomized controlled trial might help to conclusively establish whether the differences in weight loss observed in this study are statistically significant.

This study has opened the doors to different areas of service improvement. Participant feedback provided in surveys and directly to the study team have helped us refine our user journey and follow-up protocols, thus helping us increase the number of actively engaged users. Feedback has also played a significant role in informing the development of our new app platform, which will be released in early 2019.

Tables

Table 1. Demographics of evaluation study participants

Participant Characteristic	Total (N=149)	CH Group (N=97)	CH + Low Calorie Diet Group (N=52)
Age, years	55	55	56
Gender, N (%)			
<i>Male</i>	19 (13%)	11 (11%)	8 (15%)
<i>Female</i>	130 (87%)	86 (89%)	44 (85%)
Ethnicity, N (%)			
<i>White or White British</i>	136 (91%)	91 (94%)	45 (87%)
<i>Gypsy/Traveller/Irish Traveller</i>	0 (0%)	0 (0%)	0 (0%)
<i>Asian or Asian British</i>	6 (4%)	3 (3%)	3 (6%)
<i>Black, Black British or Caribbean</i>	3 (2%)	1 (1%)	2 (4%)
<i>Mixed or Multiple</i>	0 (0%)	0 (0%)	0 (0%)
<i>Other</i>	2 (1%)	1 (1%)	1 (2%)
<i>Prefer not to say</i>	2 (1%)	1 (1%)	1 (2%)
Education Levels, N (%)			
<i>High School ('O' or 'A' Levels)</i>	27 (18%)	17 (18%)	10 (19%)
<i>National Vocational Qualification (Levels 1, 2, 3, 4 or 5)</i>	11 (7%)	7 (7%)	4 (8%)
<i>Degree</i>	37 (25%)	23 (24%)	14 (27%)
<i>Post-graduate degree</i>	35 (23%)	21 (22%)	14 (27%)
<i>Professional Qualifications</i>	26 (17%)	20 (21%)	6 (12%)
<i>Other Vocational/Work-related Qualifications</i>	9 (6%)	6 (6%)	3 (6%)
<i>No Qualifications</i>	4 (3%)	3 (3%)	1 (2%)

Employment Status, N (%)			
<i>Full-time Employee</i>	55 (37%)	42 (43%)	13 (25%)
<i>Part-time Employee</i>	24 (16%)	16 (17%)	8 (15%)
<i>Self-employed (Full or Part-time)</i>	15 (10%)	11 (11%)	4 (8%)
<i>Government Supported Training Programme</i>	0 (0%)	0 (0%)	0 (0%)
<i>Full-time Education</i>	2 (1%)	1 (1%)	1 (2%)
<i>Unemployed and Available for Work</i>	5 (3%)	1 (1%)	4 (8%)
<i>Permanently sick/disabled</i>	1 (1%)	1 (1%)	0 (0%)
<i>Wholly retired from work</i>	34 (23%)	21 (22%)	13 (25%)
<i>Looking after the home</i>	8 (5%)	3 (3%)	5 (10%)
<i>Doing something else</i>	5 (3%)	1 (1%)	4 (8%)
Annual Household Income, N (%)			
<i>Up to £5,199, N (%)</i>	3 (2%)	2 (2%)	1 (2%)
<i>£5,200 and up to £10,399</i>	4 (3%)	2 (2%)	2 (4%)
<i>£10,400 and up to £15,599</i>	9 (6%)	5 (5%)	4 (8%)
<i>£15,600 and up to £20,799</i>	9 (6%)	4 (4%)	5 (10%)
<i>£20,800 and up to £25,999</i>	15 (10%)	9 (9%)	6 (12%)
<i>£26,000 and up to £31,199</i>	21 (14%)	13 (13%)	8 (15%)
<i>£31,200 and up to £36,399</i>	15 (10%)	12 (12%)	3 (6%)
<i>£36,400 and up to £51,999</i>	17 (11%)	13 (13%)	4 (8%)
<i>£52,000 and above</i>	35 (23%)	27 (28%)	8 (15%)
<i>Don't Know</i>	4 (3%)	3 (3%)	1 (2%)
<i>Prefer not to say</i>	17 (11%)	7 (7%)	10 (19%)
Household Accommodation, N (%)			
<i>Owned outright</i>	79 (53%)	47 (49%)	32 (62%)

<i>Buying on a mortgage</i>	52 (35%)	39 (40%)	13 (25%)
<i>Rent from council</i>	1 (1%)	0 (0%)	1 (2%)
<i>Rent from Housing Association/Trust</i>	4 (3%)	2 (2%)	2 (4%)
<i>Rent from private landlord</i>	9 (6%)	7 (7%)	2 (4%)
<i>Other</i>	4 (3%)	2 (2%)	2 (4%)
Marital Status, N (%)			
<i>Never Married</i>	16 (11%)	8 (8%)	8 (15%)
<i>Living with Partner (Co-habiting)</i>	14 (9%)	10 (10%)	4 (8%)
<i>Married/Civil Partnership</i>	89 (60%)	60 (62%)	29 (56%)
<i>Divorced/Civil Partnership Dissolved</i>	12 (8%)	9 (9%)	3 (6%)
<i>Widowed/Surviving Civil Partner</i>	8 (5%)	3 (3%)	5 (10%)
<i>Separated</i>	2 (1%)	2 (2%)	0 (0%)
<i>Prefer not to say</i>	8 (5%)	5 (5%)	3 (6%)
Weight, Kg	79.2	80.7	76.4
BMI, Kg/m²			
<i>Average BMI</i>	28.5	28.6	28.4
BMI Categories, N (%)			
<i>Normal (<25)</i>	51 (34%)	34 (35%)	17 (33%)
<i>Overweight (25 - 29.9)</i>	44 (30%)	25 (26%)	19 (37%)
<i>Obese (>=30)</i>	49 (33%)	33 (34%)	16 (31%)
<i>Not Known</i>	5 (3%)	5 (5%)	0 (0%)

Table 2. Uptake of Programme and Education Module Completion

Uptake/Education Module Completion	Total (N=149)	CH Group (N=97)	CH + Low Calorie Diet Group (N=52)
Programme Declined at Start, N (%)	9 (6%)	5 (5%)	4 (8%)
App Uptake, N (%)			
<i>Never Logged into App</i>	8 (5%)	6 (6%)	2 (4%)
<i>Active Users i.e Logged into App</i>	132 (89%)	86 (89%)	46 (88%)
Education Completion, N (%)			
<i>Did not Start Learning Modules</i>	8 (5%)	3 (3%)	5 (10%)
<i>Started Learning Modules</i>	124 (83%)	83 (86%)	41 (79%)
<i>Completed Learning Modules¹</i>	104 (70%)	68 (70%)	36 (69%)
<i>Did not Complete Learning Modules</i>	20 (13%)	15 (15%)	5 (10%)
Behaviour Change Coaching, N (%)			
<i>Accessed Coaching²</i>	79 (53%)	50 (52%)	29 (56%)
<i>Did not Access Coaching</i>	31 (21%)	20 (21%)	11 (21%)
<i>Declined Coaching</i>	22 (15%)	16 (17%)	6 (12%)

¹Users who completed 4 or more learning modules

²Users who booked at least one appointment with their coach

³Users who booked at least one appointment with their coach

⁴Users who booked at least one appointment with their coach

⁵Users who booked at least one appointment with their coach

Table 3. Change in Self-Reported Weight from Baseline

Timepoint	Change in Self-reported Weight from Baseline (Kg)		
	Total	CH Group	CH + Low Calorie Diet Group
Month 1	-1.0	-0.3	-1.9
Month 2	-1.8	-1.1	-3.2
Month 3	-2.5	-2.0	-3.2
Month 6	-3.3	-2.2	-4.7
Month 9	-3.6	-2.8	-4.5
Month 12	-4.5	-4.0	-5.0

Table 4. Participants Achieving 3% Weight Loss

Timepoint	Participants Achieving 3% Weight Loss, N (%)		
	Total	CH Group	CH + Low Calorie Diet Group
Month 1	11 (16%)	1 (3%)	10 (33%)
Month 2	20 (39%)	9 (27%)	11 (61%)
Month 3	26 (43%)	11 (31%)	15 (58%)
Month 6	27 (60%)	13 (52%)	14 (70%)
Month 9	20 (63%)	9 (53%)	11 (73%)
Month 12	18 (56%)	8 (57%)	10 (56%)

Table 5. Participants Achieving 6% Weight Loss

Timepoint	Participants Achieving 6% Weight Loss, N (%)		
	Total	CH Group	CH + Low Calorie Diet Group
Month 1	6 (9%)	1 (3%)	5 (17%)
Month 2	8 (16%)	2 (6%)	6 (33%)
Month 3	15 (25%)	3 (9%)	12 (46%)

Month 6	16 (36%)	6 (24%)	10 (50%)
Month 9	11 (34%)	3 (18%)	8 (53%)
Month 12	9 (28%)	3 (21%)	6 (33%)

Table 6. Participant Feedback on Programme

Programme Feature	Total	CH Group	CH + Low Calorie Diet Group
Education Content, N (%)			
<i>Easy to Understand</i>	82 (95%)	49 (96%)	33 (94%)
App Features, N (%)			
<i>Easy to Use Weight Tracker</i>	59 (69%)	36 (71%)	23 (66%)
<i>Weight Tracker Valuable</i>	69 (80%)	39 (76%)	30 (86%)
<i>Easy to Use Diet Tracker</i>	55 (64%)	29 (57%)	26 (74%)
<i>Diet Tracker Valuable</i>	38 (44%)	22 (43%)	16 (46%)
Behaviour Change Coaching, % (Average across months 1, 2, 3, 6, and 9)			
<i>Coaching Essential to Success</i>	82%	78%	87%
<i>Satisfied with Coaching</i>	82%	78%	86%
Overall Programme, % (Average across months 1, 2, 3, 6, and 9)			
<i>Confident Programme Will Help Achieve Goals</i>	81%	78%	86%
<i>Satisfaction with Programme</i>	82%	79%	86%
<i>Will Recommend to Others</i>	82%	81%	84%

